UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Master Dkt. 1:13-md-02419-FDS
THIS DOCUMENT RELATES TO: *Marko v. New England Compounding Pharmacy, Inc., et al.* Docket No. 13-cv-10404; *Pennington v. New England Compounding Pharmacy, Inc., et al*. Docket No. 13-cv-10406; *Leaverton v. New England Compounding Pharmacy, Inc., et al.* Docket No. 13-cv-10408; *Tolotti v. New England Compounding Pharmacy, Inc., et al.* Docket No. 13-cv-10413; *Zavacki v. New England Compounding Pharmacy, Inc., et al.* Docket No. 13-cv-10441; *Letizia v. New England Compounding Pharmacy, Inc., et al.* Docket No. 13-cv-10442; *Tisa v. New England Compounding Pharmacy, Inc., et al.* Docket No. 13-cv-10446; *Devilli v. New England Compounding Pharmacy, Inc., et al.* Docket No. 13-cv-11167; *Effendian v. New England Compounding Pharmacy, Inc., et al.* Docket No. 13-cv-11233; and *Guzman v. v. New England Compounding Pharmacy, Inc., et al.* Docket No. 12-cv-12208	

PLAINTIFFS' STEERING COMMITTEE'S
MEMORANDUM OF LAW IN OPPOSITION TO
PREMIER DEFENDANTS' MOTION TO DISMISS PURSUANT TO F.R.C.P. 12(b)(6)

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INTRODUCTION

It is well-recognized that the widespread outbreak of fungal meningitis, which gave rise to this multidistrict litigation, was caused by contaminated injections of preservative free methlyprednisolone acetate ("MPA") compounded by the New England Compounding Center, Inc. ("NECC") and administered to patients at numerous pain clinics, orthopedic practices and hospitals located in 23 States. See CDC[1] and FDA[2] web sites on the subject fungal meningitis outbreak; Smith, Rachel M., et al., *Fungal Infections Associated with Contaminated Methylprednisolone Injections,* N Engl J Med 2013; 369:1598-1609 (Oct. 24, 2013). It is also widely acknowledged in the medical and regulatory communities that deplorable, unsanitary conditions at NECC's facility in Framingham, Massachusetts contributed to causing what is the worst outbreak of fungal meningitis in U.S. history. While NECC and its corporate insiders certainly bear responsibility for the meningitis outbreak which resulted in numerous injuries and death to hundreds of people, they are not the only culpable party. Indeed, a significant portion of the blame for the meningitis epidemic rests with numerous doctors and healthcare facility personnel throughout the county who, for reasons of cost saving and convenience — and not medical necessity, acquired tainted MPA by mail order from a fly-by-night Massachusetts pharmacy (NECC) located hundreds of miles away from their clinics or practices.

Investigation shows that scores of doctors and medical facilities, including the Premier Defendants[3], mail ordered hundreds of vials of prescription preservative free MPA from NECC

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[1] CDC, Multistate Fungal Meningitis Outbreak Investigation, http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html ((Visited March 2014).

[2] FDA, Multistate outbreak of fungal meningitis and other infections, http://www.fda.gov/%20Drugs/DrugSafety/FungalMeningitis/default.htm.

[3] "Premier Defendants" and/or "Premier" refers collectively to Defendants Premier Orthopaedic and Sports Medicine Associates of Southern New Jersey, LLC, trading as Premier Orthopaedic Associates,

sight unseen and without any reasonable effort to vet and qualify NECC's ability to aseptically make, package, and dispense preservative free MPA.

The Master Complaint[4] filed by Plaintiffs' Steering Committee on November 5, 2013 and incorporated by reference through the filing of Short Form Complaints in the above-captioned related actions by the responding plaintiffs, sets forth in great detail the reasons why these healthcare providers, including the Premier Defendants, share responsibility for Plaintiffs' injury and harm. For it was Premier's negligent and reckless conduct in mail ordering and purchasing contaminated steroid injections and administering them to patients, which in large part, caused this tragic and deadly outbreak of meningitis. The factual and legal allegations in the Master Complaint concerning the "Clinic Related Defendants"[5] are thorough, well-pleaded, and sufficiently state claims upon which relief can be granted. They plead an actionable, multi-count case that the Premier Defendants without proper qualification of NECC's competence and ability acquired and administered adulterated preservative free MPA from NECC, and, importantly, did so by submitting prescriptions to NECC that flagrantly violated Massachusetts' controlled

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Premier Orthopaedic Associates Surgical Center, LLC, and Kimberly Yvette Smith, M.D., a/k/a Kimberly Yvette Smith-Martin, M.D.

[4] Master Complaint against UniFirst and Clinic-Related Defendants, Dkt. No. 545, as amended by Dkt. No. 832, hereinafter "Master Complaint or "Complaint."

[5] The Master Complaint lists a number of facilities that received recalled lots of MPA from NECC. Those hospitals, clinics, healthcare facilities, and their physicians, staff, agents, and employees are referred to in the Master Complaint collectively as the "Clinic Related Defendants." Compl. ¶¶ 22-23. The Premier Defendants are included in this defined term. *Id*. at 22. In addition, because the Master Complaint was adopted and incorporated by reference in each of the above-captioned related actions, the term "Clinic Related Defendants" has come to include and apply to the Premier Defendants.

substances law,[6] Massachusetts' consumer protection law[7], New Jersey's consumer protection law,[8] and New Jersey's protection prescription regulations.[9]

The Master Complaint is lengthy and describes in a detailed manner how Premier's conduct led to the outbreak. For example, the Complaint alleges that Defendants failed to exercise reasonable care to ensure that the drugs they purchased and administered to Plaintiffs were manufactured in compliance with applicable pharmaceutical laws. Master Compl. ¶ 234(a). The Complaint alleges that Premier failed to perform the necessary due diligence to determine the safety and quality of NECC's drugs and failed to determine if NECC could properly provide sterile, preservative free drugs for administration to patients. Master Compl. ¶ 234(d). The Complaint also states that Premier failed to conduct sufficient due diligence to determine whether NECC was a reputable and safe supplier of sterile injectable compounds and the Complaint asserts that Premier purchased compounded drugs in bulk from NECC without using patient specific individual prescriptions as required by law. Master Compl. ¶ 234(j)(q). In addition, the Master Complaint avers that as a result of Premier's conduct, Plaintiffs were administered contaminated products causing serious injuries and, in some cases, death. (Master Compl. ¶¶ 270, 271, 298, 303, 355).

The Master Complaint and the Short Form Complaint (by adoption and incorporation by reference) set forth the following causes of action against the Premier Defendants: Count III – Negligence and Gross Negligence; Count IV – Violation of the New Jersey Consumer Protection Statute (N.J.S.A. 56-8-1); Count VII – Battery; Count VIII – Failure to Warn; Count X –

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[6] MGL Ch. 94C §1 et seq.

[7] MGL Ch. 93A.

[8] New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 *et seq*.

[9] N.J.A.C. 13:39-7.12(requiring patient name as part of labeling); N.J.A.C. 13:39-11.21 (Same); N.J.A.C. 13:35-7.2 (requiring a prescription to contain the patients full name, address and age.

Agency; Count XI – Civil Conspiracy; Count XIII – Loss of Consortium; Count XIV – Punitive Damages. On January 31, 2014, Premier Defendants filed the instant Rule 12(b)(6) Motion to Dismiss seeking dismissal of each cause of action. However, for the reasons below, Plaintiffs have more than adequately stated their claims and Premier Defendants' Motion to Dismiss should be denied.

STANDARD OF REVIEW

In deciding a motion to dismiss, "a court does not rule on the evidentiary sufficiency of a complaint, only on whether its factual and legal assertions allege 'a plausible entitlement to relief.'" *Balerna v. Gilberti*, 2010 U.S. Dist. LEXIS 124639 (D. Mass. Nov. 24, 2010); (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 559 (2007)). "In considering a motion to dismiss, the court should accept as true all well-pleaded allegations and should view the complaint in a light most favorable to the plaintiff." On a motion to dismiss, the Court must "treat as true all well-pleaded facts, viewing those facts in the light most favorable to the plaintiff, and drawing all reasonable inferences therefrom for him." *Knowlton v. Shaw*, 704 F.3d 1 (1st Cir. 2013).

Under Federal Rule of Civil Procedure 12(b)(6), a court may grant a motion to dismiss if the complaint fails to state a claim upon which relief can be granted. The United States Supreme Court held that, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, . . . a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do[.]" *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (internal citations omitted).

LEGAL ARGUMENT

I. PLAINTIFFS HAVE MORE THAN ADEQUATELY STATED COGNIZABLE CLAIMS FOR NEGLIGENCE AND FAILURE TO WARN AND THESE CENTRAL CLAIMS SHOULD NOT BE DISMISSED.

i. Plaintiffs' Claims for Negligence and Failure to Warn are Not Subsumed by the New Jersey Product Liability Act Because Plaintiffs Were Harmed by *Defendants' Conduct* in Addition to a Defective Product.

The Premier Defendants contend that Plaintiffs' Count III – Negligence and Gross Negligence and Plaintiffs' Count VIII – Failure to Warn[10], must be dismissed. Defendants argue that these counts are based solely on harm caused by an allegedly defective product, i.e. the contaminated injectable steroid MPA, and therefore, the New Jersey Product Liability Act ("NJPLA") is the exclusive remedy regardless of the legal theory supporting the case. Contrary to the Premier Defendants' contentions, New Jersey jurisprudence recognizes negligence and lack of informed consent as viable claims that can be asserted against healthcare providers for the negligent performance of their services even when a defective product may also be involved.

In *Snyder v. Mekhjian*, 582 A.2d 307 (N.J. Super. Ct. App. Div. 1990), for example, Plaintiff contracted Acquired Immune Deficiency (AIDS) as a result of receiving a contaminated blood transfusion during a surgical procedure. *Id*. at 309. Plaintiff was permitted to proceed on a theory of negligence against the physicians and the hospital. *Id*. at 313. Specifically, Plaintiff alleged that Defendants failed to inform the Plaintiff of the risk of receiving contaminated blood products; failed to provide the Plaintiff with the option to pre-bank his own blood; and/or failed to arrange to have family members donate blood prior to surgery. *Id*. at 286. Plaintiff was also permitted to pursue a negligence action against the blood bank for failing to implement appropriate screening procedures of the donor blood. *Id*. at 287. Similarly, in *Estate of Elkerson*

[10] Plaintiffs' Count VIII – Failure to Warn is equivalent to a claim for Lack of Informed Consent.

v. North Jersey Blood Center, 776 A.2d 244 (N.J. Super. Ct. App. Div. 2001), a Plaintiff who contracted hepatitis after receiving tainted blood was permitted to proceed against the blood bank for its failure to perform available testing upon the blood to ensure its safety. *Id*. at 223. In both *Snyder* and *Elkerson*, Plaintiffs alleged that the Defendants' negligence enhanced the risk of contracting AIDS and hepatitis, respectively.

Likewise, in *Johnson v. Mountainside Hosp.*, 571 A.2d 318 (N.J. Super. Ct. App. Div. 1990), a wrongful death action wherein Plaintiff suffered brain damage and died after being accidently disconnected from a respirator, Plaintiff alleged, *inter alia*, that the respirator was a defective product and instituted a lawsuit against the manufacturer of the respirator, the hospital and the physicians. *Id*. at 321. Plaintiff alleged that the hospital, as a commercial lessor of the respirator equipment, should be strictly liable for the defective respirator. *Id*. Although the Court would not permit the Plaintiff to proceed against the hospital under a theory of strict liability, the Court did permit Plaintiff to proceed against the hospital and the physicians based upon theories of negligence in the performance of their services. *Id*.

Based upon the cases of *Snyder*, *Elkerson*, and *Johnson*, it is clear that the fact that a defective product is involved in a medical malpractice matter does not mandate that the NJPLA is the exclusive remedy against the healthcare providers.

The Port Authority of New York and New Jersey v. Arcadian Corp., 189 F.3d. 305 (3rd. Cir. 1999), which Defendants rely upon to support their contentions that Plaintiffs do not have a viable negligence claim, is inapplicable. In *Port Authority*, the Defendants were manufacturers of fertilizer products employed by terrorists to create explosives used in the 1993 World Trade Center bombing. *Id*. at 309. The Port Authority Court ultimately determined that the fertilizer manufacturers owed no duty and were not the proximate cause of the World Trade Center

bombing and concluded that the Plaintiff had failed to state a claim. *Id*. at 313, 317. The *Port Authority* Court also reviewed Plaintiffs' allegations of negligence wherein they asserted that the Defendants negligently failed to design, manufacture, market, distribute and/or sell the products with a formulation that would eliminate their explosive properties and determined that these allegations were essentially allegations equivalent to a products liability cause of action and fell within the NJPLA. *Id*. at 310. Plaintiffs' Complaint in the present matter does not assert any negligence claims against the Premier Defendants for the negligent *manufacture* of the contaminated MPA, but rather asserts, *inter alia*, negligence was committed in the performance of their medical services associated with obtaining and administering preservative free MPA from an unaccredited compounding pharmacy namely, NECC. Therefore, Plaintiffs' claims for negligence and lack of informed consent remain viable under New Jersey law.

Given that negligence and lack of informed consent[11] are viable claims, the Court must next determine whether Plaintiffs' Complaint provides sufficient factual allegations in support of these claims. A review of the Master Complaint reveals that Plaintiffs have sufficiently asserted claims for negligence and lack of informed consent in connection with the services provided by the Premier Defendants. Specifically, Plaintiffs' Complaint provides the following:

> 227. The Clinic Related Defendants had a duty to exercise reasonable care to ensure that the drugs they purchased in order to sell and administer to their patients, including Plaintiffs, were purchased from drug companies that complied with the laws regarding pharmaceuticals.

[11] In *Baird v. American Medical Optics*, 693 A.2d 904 (N.J. Super. Ct. App. Div. 1997), Plaintiff filed suit after suffering injuries following implantation of an experimental ocular lens which was not FDA approved. Plaintiff alleged that Defendant Hospital had a duty to obtain informed consent from those undergoing experimental treatment. Id. at 907. The Appellate Court left open the possibility that a hospital may have a duty of informed consent, holding, "Whether the duty exists may depend on the facts, the relationship between the hospital and doctors, and the ultimate findings regarding the doctor's conduct. We therefore conclude that the issue should be decided after development of a full record." *Id*. (citations omitted). Accordingly, whether Premier owed a duty of informed consent to advise Plaintiffs that they were using MPA purchased from a compounding pharmacy and not from an FDA approved manufacturer, should be decided after completion of discovery and not at the motion to dismiss stage.

228. The Clinic Related Defendants had a duty to exercise reasonable care to ensure that the drugs they provided to their patients, including Plaintiffs, were purchased from a company that made safe and effective drugs.

229. The Clinic Related Defendants had a duty to exercise reasonable care to ensure that the drugs they provided to their patients, including Plaintiffs, were purchased from a company that utilized proper quality control, safety, and sterility measures in order to minimize the possibility that the drugs would become adulterated or contaminated.

230. The Clinic Related Defendants had a duty to exercise reasonable care to avoid administering contaminated drugs, or drugs they knew or should have known to be contaminated, to Plaintiffs.

231. The Clinic Related Defendants had a duty to provide Plaintiffs with reasonable care and treatment.

232. The Clinic Related Defendants had a duty to obtain informed consent from Plaintiffs for the procedure performed on Plaintiffs, adequately and accurately describing to Plaintiffs the nature of the procedure, as well as the risks of such procedure, including the drugs that were to be administered during such procedure.

233. In this case, where the drug came from an unaccredited, mass producing, out-of-state, compounding pharmacy, unregulated by the FDA, the Clinic Related Defendants had a duty to inform Plaintiffs of the source of the drug and the dangers associated therewith.

234. The Clinic Related Defendants breached their duties to Plaintiffs in many respects, including, without limitation:

a. The Clinic Related Defendants failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to Plaintiffs were made by NECC in compliance with all applicable pharmaceutical laws;

b. The Clinic Related Defendants failed to exercise reasonable and prudent care to ensure that the drug they purchased and provided to Plaintiffs were sold to them by NECC in compliance with all applicable pharmaceutical laws;

c. The Clinic Related Defendants failed to know and understand the source and supply of the drug they provided to Plaintiffs;

d. The Clinic Related Defendants failed to use the appropriate, necessary and reasonable due diligence and investigatory steps and measures necessary to vet, evaluate and determine the safety and quality of NECC's drugs, and in particular, determine if NECC could properly and suitably compound, package and provide sterile preservative free drugs for administration to Plaintiffs;

e. The Clinic Related Defendants failed to follow the reasonable ASHP Guidelines on Outsourcing Sterile Compounding Services, which had

they followed, would have established that NECC's products were unsuitable for administration to the Plaintiffs;

f. The Clinic Related Defendants failed to exercise reasonable and prudent care to ensure that the drug they provided to Plaintiffs were produced in sanitary, sterile conditions;

g. The Clinic Related Defendants failed to properly inform Plaintiffs that the use of the drug was not approved by the FDA;

h. The Clinic Related Defendants failed to properly inform Plaintiffs of the risks and dangers associated with the administration of the drug; and they failed to inform them that they had obtained the drug from NECC, a mass-producing, unaccredited, non-FDA regulated compounding pharmacy;

i. The Clinic Related Defendants failed to exercise reasonable care to avoid administering to Plaintiffs an adulterated, contaminated and unreasonably dangerous drug;

j. The Clinic Related Defendants failed to conduct adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;

k. The Clinic Related Defendants failed to visit NECC's facilities before procuring compounded drugs, and other medicines, from NECC;

l. The Clinic Related Defendants failed to investigate and exercise sufficient due diligence before administering drugs procured from NECC, including failing to investigate or inquire concerning NECC's compounding practices, standard operating procedures, pharmacist training, and risk management protocols;

m. The Clinic Related Defendants failed to determine whether NECC had a history of recalling compounded medications before procuring medicines from that company;

n. The Clinic Related Defendants failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring drugs from NECC;

o. The Clinic Related Defendants failed to determine whether NECC had a history of product liability suits before procuring medicines from that company;

p. The Clinic Related Defendants failed to keep abreast of the dangers of sterile compounding;

q. The Clinic Related Defendants purchased compounded drugs in bulk from NECC without using patient specific individual prescriptions;

r. Many of the Clinic Related Defendants failed to appropriately store drugs purchased from NECC to reduce the risk of the growth of contaminants;

s. The Clinic Related Defendants failed to adequately supervise and train the physicians, nurses, agents and employees who ordered drugs from NECC;

t. The Clinic Related Defendants failed to implement policies and procedures that would prevent the procurement of purportedly sterile drugs from an out-of-state compounding pharmacy with a deplorable facility and sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;

u. The Clinic Related Defendants administered drugs to Plaintiffs' without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;

v. The Clinic Related Defendants failed to promptly notify Plaintiffs that they were injected with potentially contaminated steroids and failed to recommend that they receive prompt treatment of their potential infections and other symptoms; and

w. The Clinic Related Defendants failed to exercise reasonable care in such other manners as may be shown through discovery and at trial.

(*See*, Master Complaint.)

In relevant part, Count VIII – Failure to Warn, of Plaintiffs' Complaint states, as follows:

> 301. The Clinic Related Defendants failed to inform their patients, including Plaintiffs, that they were being administered an unsafe, unreasonably dangerous drug compounded by NECC rather than a high quality drug produced by an FDA regulated manufacturer.
>
> 302. Many, if not all, of the Clinic Related Defendants prepared a Consent for Treatment Form. The form, which was presented to Plaintiffs by the Clinic Related Defendants, and which Plaintiffs read and relied upon when agreeing to accept treatment, failed to inform the Plaintiffs of the risks and benefits of the procedures before it was performed. When presenting the form to Plaintiffs, the Clinic Related Defendants knew that nobody on its behalf would be informing Plaintiffs of the inferior and unreasonably dangerous nature of the NECC drug that would be administered to Plaintiffs. Clinic Related Defendants knew that if Plaintiffs were informed of the true nature of the NECC drugs, Plaintiffs would decline treatment with NECC drugs, threatening the Healthcare Providers' profits.
>
> 303. As a proximate result of the Clinic Related Defendants' wrongful conduct, Plaintiffs suffered grievous bodily injury and/or death, have required extensive medical treatment, have incurred and in the future will incur substantial

> medical bills and have suffered and will in the future suffer inconvenience and severe mental anguish."

(*Id.*)

Thus, the detailed averments above demonstrate that the Master Complaint provides sufficient factual allegations to support Plaintiffs' claims for negligence and lack of informed consent in Counts III and VIII, respectively, of their complaint.

ii. Plaintiffs Concede That If Premier Defendants Are Not Deemed Sellers As Defined by the New Jersey Product Liability Act Then Dismissal of This Claim Is Warranted.

The Premier Defendants challenge the Master Complaint to the extent it purports to set out product liability claims under the New Jersey Product Liability Act. ("NJPLA"). N.J.S.A. 2A:58C-1 *et seq*. Defendants are correct that the NJPLA codified a common law rule that healthcare providers are generally not subject to strict liability claims based upon defective products tangentially used in connection with medical treatment.[12] See, N.J.S.A. 2A:58C-8. This provision of the NJPLA statutorily defines a product seller to not include "[a] provider of professional services in any case in which the sale or use of a product is incidental to the transaction and the essence of the transaction is the furnishing of judgment, skill or services." That said, the fact that the NJPLA excludes from its scope products provided and sold by healthcare providers incidental to their medical care does not end the matter as to healthcare

[12] The NJPLA differs in a significant way from the Tennessee Product Liability Act, Tenn. Code. Ann. sec. 29-26-101 et. seq.: Tennessee's Act specifically permits assertion of a products liability claim against a seller of a product where certain conditions are met, such as the judicial declaration of insolvency of the manufacturer or where the manufacturer is not amenable to service of process in Tennessee. Tenn. Code Ann. sec. 29-26-106(4) & (5). Moreover, the Tennessee Act contains no such specific exclusion of claims where the sale of a product is related to the provision of medical services. In fact, the Tennessee Act contemplates claims against sellers in the health care context and provides limited exclusions in certain medical-related circumstances not implicated by the fungal infection cases. Tenn. Code Ann. sec. 29-28-103(c)(2) ("**For purposes of this subsection (c) only** [relating to silicone breast implants], "seller" does not include a hospital or other medical facility where the procedure took place, nor does "seller" include the physician or other medical personnel involved in the procedure.") (emphasis added). In other words, under the Tennessee Act, defendants who sold the contaminated substances to patients can be held liable under a products liability theory.

professional's liability where a defective drug or device is involved in causing a patient's injures. The fact the NJPLA does not cover products sold or billed for by a healthcare provider calls into play a corollary rule developed in New Jersey jurisprudence that where a NJPLA claim does not exist due to the acts provisions excluding it, then other possible legal claims that arise out of the transaction or conduct are held not to be "subsumed" under the NJPLA's exclusive remedy provisions. See e.g., *Montich v. Miele USA, Inc.*, 849 F. Supp. 2d 439, 449 (D.N.J. 2012) (Collecting and analyzing New Jersey cases and permitting implied warranty claims to proceed).

Since Premier contends it cannot be held liable under the NJPLA, to the extent that factual predicate is proven, then claims sounding in professional negligence and claims under the consumer statutes are not subsumed and remain viable. Accordingly, if Defendants are correct that the administration of MPA falls outside the ambit of the NJPLA because the use of NECC's MPA was incidental to the transaction, then the subsumation arguments that Premier makes in the previous section fail for this reason as well. Conversely, to the extent Premier cannot satisfy the factual predicate needed to exclude themselves as a "product seller" from the NJPLA, then the PLA applies and its Motion seeking dismissal of this alternative claim should be denied.

II. THE MASTER COMPLAINT STATES A VALID CAUSE OF ACTION FOR BATTERY AGAINST THE PREMIER DEFENDANTS.

Count VII of the Master Complaint asserts a cause of action for battery against the Clinic Related Defendants, including the Premier Defendants. It specifically alleges that the Defendants injected a harmful substance (an adulterated drug) into the Plaintiffs, including fungal or bacterial contamination, and that the Plaintiffs did not consent to the injection of contaminated drugs into their bodies. Moreover, the drug was called or referred by Defendants in its medical records, documentation and billing as Depo-medrol, a materially different drug in that, besides being a brand name for a manufactured FDA approved steroid, it contains

preservatives. Contrary to the Defendants' argument, New Jersey law does permit a cause of action for battery in the medical care context where the procedure performed is substantially different from the procedure for which consent has been given. *Murphy v. Implicito*, 2005 WL 24447776 (N.J. Superior Court, App. Div. 2005). Therefore, Defendants' Motion to Dismiss Count VII of the Master Complaint for failure to state a claim upon which relief can be granted should be denied.

In *Murphy v. Implicito*, the plaintiff had consented to the performance of a lumbar discectomy and fusion "with iliac crest bone graft." In the course of performing this procedure, the physicians used a commercially processed cadaver bone to complete the bone graft. Plaintiff claimed that he had not known that cadaver bone would be used and did not consent to its use. The Appellate Court held that consent to the surgery did not include consent to the use of the cadaver bone and that the use of the cadaver bone without plaintiff's consent constituted battery. The Court stated "[a]ccordingly, plaintiff has demonstrated a *prima facie* cause of action for battery and may be entitled to such damages as may flow from the battery." *Id*. at 8.

Here, although Plaintiffs consented to the injection of steroids into their body, they did not consent to injection of contaminated bacterial fungal and bacterial substances. Nor did they ever consent to the administration of a mail ordered medication from an unaccredited, non FDA approved compounding pharmacy they never heard of, was located hundreds of miles away and that their doctors and their practice had never visited or otherwise seen. Consequently, the consent is vitiated and a cause of action for battery has been stated.

In *Murphy*, the Court recognized that battery "may occur not only when no consent is obtained from the patient prior to the medical procedure, but also when the scope of consent is exceeded by a physician." *Id.* The Court quoted from the Restatement (Second) of Torts,

Section 892A providing that, "If the actor exceeds the consent, it is not effective for the excess." Thus, the consent to be injected with a steroid cannot provide a shield for liability for injecting the mail ordered preservative free steroid medication contaminated with harmful substances to which the Plaintiffs did not consent.

In this vein, the *Murphy* Court cited with approval the California case of *Ashcraft v. King*, 228 Cal. App. 3d 604 (1991), a case similar to the issues presented here. In *Ashcraft*¸ the plaintiff consented to an operation but alleged that the consent was conditioned on using only blood that had been donated by the plaintiff's family during the course of the operation. Although plaintiff's family members did donate blood to the hospital, none of that was used in the operation. Instead, she was given blood from the general supplies on hand at the hospital and it was later determined that the blood was contaminated with HIV. The Court held that these facts established a cause of action for battery. "In an action for civil battery the element of intent is satisfied if the evidence shows defendant acted with a 'willful disregard of plaintiff's rights.' In the context of battery in a medical procedure, 'when the patient gives permission to perform one type of treatment and the doctor performs another, the requisite element of deliberate intent to deviate from the consent given is present.'" *Id.*, 228 Cal. App. 3d at 612, quoting *Cobbs v. Grant*, 8 Cal. 3d 229, 240 (1972).

The *Murphy* Court also cited with approval the Arizona case of *Duncan v. Scottsdale Medical Imaging, Ltd.*, 205 Ariz. 306 (2003). In that case the Arizona Supreme Court held that a healthcare provider had committed a battery by injecting the plaintiff with Fentanyl, a sedative. The evidence showed that the plaintiff had consented to the administration of a sedative, but insisted that she would not consent to any sedative except for Demerol or Morphine. The Court

held that the consent to be injected with Demerol or Morphine did not relieve the healthcare provider from liability for injecting the Fentanyl. The Court stated the following:

> The relevant inquiry here is not whether the patient consented to an injection; the issue is whether the patient consented to receive the specific drug that was administered. We hold that when a patient gives limited or conditional consent, a health care provider has committed a battery if the evidence shows the provider acted with willful disregard of the consent given. See *Ashcraft v. King*, 228 Cal.App.3d 604, 278 Cal.Rptr. 900, 904 (1991) (surgeon committed battery when patient's consent to operation was conditioned on use of family-donated blood only, and surgeon intentionally violated condition)… [Defendant] admitted that Duncan presented a viable battery claim because Nurse Fink injected her with a painkiller which she had expressly rejected.

Id., 205 Ariz. at 311. Here, the fact that the Plaintiffs had consented to receive an injection of a steroid does not relieve Defendants from liability for a battery for injecting them with the contaminated substance.

The Premier Defendants injected the Plaintiffs with preservative free MPA compounded from a non accredited, pharmacy that contained contaminating fungal microbes. They did not obtain the consent of any Plaintiff to be injected with that contaminated material. Nor did they consent to the administration of a steroid not manufactured and packaged in an FDA approved manufacturing facility. Consequently, the procedure constituted an unlawful battery. Therefore, Defendant's motion to dismiss Count VII of the Master Complaint must be denied.[13]

[13] The Master Complaint also contains a count asserting the Defendants' liability under the Informed Consent Doctrine. Defendants have not moved to dismiss that Count. However, in a footnote in their Memorandum of Law, they assert that the corporate Defendants Premier Orthopedics and Premier Surgical Center owed no duty to obtain the informed consent of patients receiving treatment at their facilities, citing *Carr v. Brezel*, 2006 WL 657380 (N.J. Super. Ct. App. Div. 2006). In *Carr*, the Court noted that the physician performing surgery at the hospital was not an employee of the hospital and that the plaintiff had not presented any expert evidence supporting a claim that the hospital, as opposed to the independent physician, should have obtained informed consent from the patient. That case has no applicability to this action. Here, the Master Complaint clearly alleges that the individual physicians are employees and agents acting on behalf of the clinic-related defendants. Master Compl. ¶ 23. Thus, the Plaintiffs' claims for failure to obtain informed consent may proceed against all of the Clinic Related Defendants.

III. PLAINTIFFS HAVE MORE THAN ADEQUATELY STATED A COGNIZABLE CLAIM FOR CIVIL CONSPIRACY AND THIS CLAIM SHOULD NOT BE DISMISSED.

A civil conspiracy is "a combination of two or more persons acting in concert to commit an unlawful act, or to commit a lawful act by unlawful means, the principal element of which is an agreement between the parties to inflict a wrong against or injury upon another, and an overt act that results in damage." *40 Morgan v. Union County Bd. of Chosen Freeholders*, 268 N.J. Super. 337, 364 (App. Div. 1993), *certif. denied*, 135 N.J. 468 (1994).

To survive a Rule 12 motion to dismiss for failure to state a claim, a plaintiff's allegations need only "be sufficient to describe the general composition of the conspiracy, some or all of its broad objectives, and the defendant's general role in that conspiracy." *Rose v. Bartle*, 871 F.2d 331, 366 (3d Cir. 1989) (internal quotations omitted). Additionally, "the plaintiff need not provide direct evidence of the conspirators' agreement; it is enough that it could be circumstantially inferred from the facts that the conspirators had reached an understanding." *Doherty v. Hertz Corp.*, No. 10-0359, 2010 U.S. Dist. LEXIS 124714, at *24 (D.N.J. Nov. 24, 2010) (citing Morgan, 268 N.J. Super. at 363-64). Additionally, when pleading civil conspiracy a plaintiff need not show that all actors engaged in the underlying tortious conduct. *See Morganroth & Morganroth v. Norris, McLaughlin & Marcus, P.C.*, 331 F.3d 406, 415 ("Not every conspirator must commit an overt act in furtherance of the conspiracy, so long as at least one does."). Rather, a defendant can be held liable for a conspiracy if it understands the general objectives of the scheme, accepts them, and agrees, either explicitly or implicitly, to do some part to further them." *Jones v. Chicago*, 856 F.2d 985, 992; *Banco Popular N. Am. v. Gandi*, 184 N.J. at 161, 177 (2005.

A review of the master complaint reveals that Plaintiffs have sufficiently asserted claims for civil conspiracy in connection with the services provided by the Premier Defendants. Specifically, Plaintiffs' complaint provides the following:

> 338. The Clinic Related Defendants acted in concert with NECC, its agents and employees, to accomplish the unlawful purpose of circumventing Massachusetts Board of Pharmacy **patient safety requirements**. Those Defendants accomplished that unlawful purpose via the unlawful means of using bogus patient lists to accompany orders of MPA.
>
> 339. The Clinic Related Defendants were involved in a conspiracy in connection with NECC's scheme to wrongfully mislead the Massachusetts Pharmacy Board (the "Board") related to NECC's attempted compliance with the Board's rules and regulations and the Clinic Related Defendants willfully, intentionally, and/or recklessly participated in the conspiracy. The conspiracy resulted in NECC being able to maintain compliance with the Board's Rules and Regulations when in fact it was not in such compliance. The Board's **rules and regulations are in place to ensure patient safety, and a natural and anticipated outcome from intentional and willful violation of the Board's rules and regulations would be the compromise of patient health and safety**. Such Board rules include, but are not limited to, 105 CMR § 700.12.
>
> 340. The conspiracy principally involved NECC's request that the Clinic Related Defendants provide patient names for patients the Clinic Related Defendants intended to provide with MPA or other pharmaceuticals. The Clinic Related Defendants, however, could not provide such patient lists and NECC requested the Clinic Related Defendants submit any list of names to be provided to the Board. The Clinic Related Defendants then complied with the request by submitting a list of patients, regardless of whether those patients actually were or would be prescribed MPA or other NECC drugs.
>
> 341. The Clinic Related Defendants knew or reasonably should have known that patient specific names were required by virtue of the fact that NECC's standard order form for MPA and other drugs requested patient specific information. Instead of filling out these standard forms properly, the Clinic Related Defendants ordered NECC pharmaceuticals in bulk and thereafter submitted list of patient names, regardless of whether those patients received the ordered pharmaceuticals.
>
> 342. The Clinic Related Defendants were aware of NECC's intent to use such patient lists in order to subvert Massachusetts Board of Pharmacy requirements.
>
> 343. For example, the Saint Thomas Outpatient Neurosurgical Center ("St. Thomas Neurosurgical"), one of the Clinic Related Defendants, placed its first order with NECC on or about June 10, 2011. That order consisted of 500 80 mg/1mL vials of MPA and 200 80 mg/2mL vials of MPA.
>
> 344. The June 2011 order form submitted by St. Thomas Neurosurgical did not contain any patient names despite the fact that the order form included a column for that information.
>
> 345. NECC sent invoices to St. Thomas Neurosurgical evidencing five separate purchases by St. Thomas Neurosurgical of five-hundred 80 mg/vials of MPA as reflected in invoices dated June 6, 2012, June 26, 2012, July 25, 2012, August 13, 2012 and August 31, 2012.

> 346. In early to mid-2012, an NECC representative informed Ms. Debra Schamberg, the St. Thomas Neurosurgical's facilities director that NECC needed St. Thomas Neurosurgical to submit a list of patients with each order in order to comply with Massachusetts Board of Pharmacy rules.
>
> 347. Ms. Schamberg told the NECC representative that she could not predict which patients would receive MPA. The NECC representative indicated that a list of previous patient names would suffice.
>
> 348. Dr. John Culclasure, St. Thomas Neurosurgical's Medical Director, and Ms. Schamberg, acting on behalf of St. Thomas Neurosurgical, provided NECC with a list of previous patients' names (including Mickey Mouse) with their order(s) for MPA from NECC.
>
> 349. Upon information and belief the other Clinic Related Defendants had similar communications with NECC.
>
> 350. The concerted action of NECC and Healthcare the Provider Defendants resulted in harm to Plaintiffs.
>
> 351. The Clinic Related Defendants are liable for the acts of their co-conspirator NECC.

(Master Complaint) (Emphasis Added).

Premier Defendants claim that the Master Complaint "fails to allege an agreement between Premier and NECC in any particularity or any agreement between any clinic or hospital and NECC." (Motion to Dismiss at Section III, para. 5). Defendants cite *Lewis v. Airco, Inc.*, stating, "[i]t should be noted that the reported cases sustaining civil conspiracy claims are based on underlying intentional torts." N.J. Super. Ct. App. Div. July 15, 2011. *See* Motion to Dismiss p. 13. However, Defendants fail to mention that *Lewis* specifically states: "We could not find any New Jersey State court opinions addressing the issue of whether the tort underlying a civil conspiracy claim must be intentional." *Id.* at *32. Nevertheless, the civil conspiracy between Premier and NECC involved an underlying intentional tort in that both Defendants acted in concert with the intent to circumvent Massachusetts pharmacy law. The Master Complaint allegations set forth a true conspiracy between NECC and Premier. Recognizing a higher risk of contamination from compounded drugs than from commercially manufactured drugs, Massachusetts law requires drugs compounded in Massachusetts be compounded for individual

patients rather than compounded in bulk. The protection afforded by this statute was for the benefit of patients receiving the drugs as alleged in paragraphs 338 and 339 of the Master Complaint. The violation involved concerted action between NECC and Premier. NECC requested that Premier submit false patient prescriptions and overlooked the falsity of the prescriptions submitted. Premier submitted false prescriptions at the request of NECC. Both conspirators understood that the purpose of their concerted action was to avoid compliance with Massachusetts law. The result of the agreement was the circumvention of Massachusetts law: Premier purchased compounded drugs in bulk from NECC, thereby depriving the ultimate users of the protection of the law.

The Master Complaint alleges that, as a Clinic Related Defendant, Premier willfully, intentionally, and/or recklessly participated in a conspiracy in connection with NECC's scheme to wrongfully mislead the Massachusetts Pharmacy Board (the "Board") related to NECC's purported compliance with the Board's rules and regulations. The conspiracy between NECC and Premier resulted in "NECC being able to maintain compliance with the Board's Rules and Regulations when in fact it was not in such compliance." The Complaint further alleges that the "Board's rules and regulations are in place to ensure patient safety, and a natural and anticipated outcome from intentional, willful, and/or reckless violation of the Board's rules and regulations would be the compromise of patient health and safety." (See Plaintiffs' Master Complaint).

Premier concedes that New Jersey law recognizes civil conspiracy. New Jersey law specifically recognizes an action for civil conspiracy where the conspirators act in concert to violate a statute designed to protect the public. Premier cites *Board of Education of Asbury Park v. Hoek*, which upholds a cause of action for conspiracy to violate a New Jersey statute brought by the party the statute was designed to protect. 38 N.J. 213, 238-39 (1962). The statute

provided bidding requirements for work contracted by School Boards. *Id.* at 222-23. The action concerned an executed carpentry contract. *Id.* It was alleged that the business manager of the School Board and the contractor conspired to violate the statute, thereby denying the benefit of the statute to the School Board (i.e., the provision of more economical services). *Id.* at 223. The New Jersey Supreme Court found that a conspiracy to violate the statute was actionable by the intended beneficiary of the statute, the School Board. *Id.* at 231.

Thus, the above allegations demonstrate that the Master Complaint provides sufficient factual support for Plaintiffs' claims for civil conspiracy in Count XI of their Complaint.

IV. THE LEARNED PROFESSIONAL DOCTRINE IS INAPPLICABLE TO PLAINTIFF'S NEW JERSEY CONSUMER FRAUD ACT CLAIM IN THIS MATTER.

The Premier Defendants claim that under a judicially created learned profession exception to the New Jersey Consumer Fraud Act ("NJCFA"), they cannot be found liable under the NJCFA, which is one of Plaintiffs' alternative liability claims. That is not the law of New Jersey.[14]

New Jersey courts do recognize a limited exception to the broad reach of the CFA for certain claims against "learned professionals." However, it is clear from New Jersey case law, that professionals have no blanket exception, and are subject to the CFA when they are acting outside of their professional capacity. *See Macedo v. Dello Russou*, 178 N.J. 340, 346 (2004) (Court does "not . . . suggest that Dr. Dello Russou would be insulated from the restraints of the

[14] Neither is it the law of Massachusetts with respect to the Commonwealth's analog to the New Jersey CFA, Mass. Gen Law Ch. 93A. See, e.g., *Darviris v. Petros*, 442 Mass. 274, 279 (Mass. 2004) (Observing that consumer protection statutes may be applied to the entrepreneurial and business aspects of providing medical services such as advertising and billing); *Soderstrom v. Beaumont Nursing Home, Inc.*, 25 Mass. L. Rep. 12 (Mass. Super. Nov. 4, 2008) (sustaining claims under Ch. 93A based on nursing home's alleged violations of state and federal regulations related to staffing requirements at nursing homes, failure to meet staffing requirements and misrepresentations about the quality of care).

CFA if he acted outside his professional capacity"); *Blatterfein v. Larken Assocs.*, 323 N.J. Super. 167, 183 (App. Div. 1999) (architect's involvement in new home construction did not trigger learned professions exception where architect's fee was incorporated into the price of the homes); *S&D Environmental Services, Inc. v. Rosenberg Rich Baker Berman & Co., P.A.*, 334 N.J. Super. 305, 320 (Law Div. 1999) (declining to dismiss CFA claim where "the alleged wrongful conduct by [accountants] did not involve plaintiff's rights as clients of any professional but instead were linked to and were instrumental in a transaction covered by the Act").

"While professionals do not seem to be *per se* exempt from the CFA they do not seem to be *per se* covered, either. Discerning whether or not a professional is subject to the CFA in a particular circumstance will depend on a number of factors including the degree and type of regulation that a professional's activities are subject to outside of the CFA and the type of transaction involved." *Waterloov Gutter Protection Systems, Inc. v. Absolute Gutter Protection, LLC*, 64 F. Supp. 2d 398, 422 (D.N.J. 1999) (citation omitted). Accordingly, New Jersey courts have applied the learned professional exception in only two circumstances: first, to allegations of professional negligence and malpractice; and second, to allegations of deceptive advertising of professional services, when such advertising is regulated by a professional body. *See DePetris, New Jersey Consumer Fraud Act & Forms* § 2.3-1:3 at 933-34 (2013 ed.).

The gravamen in every successful assertion of the learned professional exemption in New Jersey, however, has been that the subject matter of the CFA litigation directly involved matters relating to core professional services provided by the professional or the quality of the service. See, e.g., *Macedo v. Dello Russou*, 178 N.J. at 346 (doctor's advertising "made in his professional capacity regarding his professional services"); *Hampton Hosp. v. Bresan*, 288 N.J. Super. 372, 383 n.3 (App. Div. 1996) (hospital medical staff's decision to recommend continued

treatment involved "services rendered . . . pursuant to medical judgment"); *Vort v. Hollander*, 257 N.J. Super. 56, 60, 63 (App. Div. 1992) (affirming summary judgment on CFA claims "deal[ing] with a lawyers [sic] performance," where jury "necessarily had to review and discount the allegations that the legal services were not adequately rendered").

However, where the misconduct is not a matter concerning professional judgment relating to a specific patient's treatment or does not involve an assessment about the quality of the professional services delivered to a specific patient according to applicable professional standards, the case law holds the exception does not apply. *See Boldt v. Correspondence* Management, *Inc.*, 320 N.J. Super. 74 (App. Div. 1999). *Accord*, *Darviris v. Petros*, 442 Mass. 274, 279 (Mass. 2004) (Consumer protection statutes may be applied to the entrepreneurial and business aspects of providing medical services such as advertising and billing).[15]

Two New Jersey decisions concerning liability of a healthcare provider under the CFA illustrate this distinction. In *Boldt v. Correspondence* Management, *Inc., supra*, a New Jersey appellate court reinstated CFA claims against doctors and found concurrent jurisdiction with respect to CFA claims against a hospital where the plaintiff alleged that the defendants failed to comply with regulation governing copying charges for medical records - an issue that did not involve the exercise of professional skills and judgment. Conversely, in *Hampton Hosp. v. Bresan*, 288 N.J. Super at 383 n.3, the court found that the learned professional exception applied

[15] The New Jersey Supreme Court's decision in *Macedo, supra text*, does not really disagree with the policy behind weight of authority to allow UDAP claims based on medical practice advertising as recognized by the Massachusetts Supreme Court in *Darviris.* A crucial step in the *Macedo* Court's reasoning to not extend the CFA to claims based on doctor's advertising was not a belief that business and entrepreneurial activities should be wholesale exempted from the purview of the CFA, but rather that the New Jersey legislature could not have intended to regulate physicians' advertising when it passed the Consumer Fraud Act in 1960 because such advertising was prohibited until 1978. 178 *N.J.* at 343-44 and n. l. Doctors, on the other, have long had the authority to make prescriptions of controlled substances and recommendations of medicine at the time the CFA was enacted.

to hospital staff's decision to recommend continued treatment, a medical decision the court expressly found to have involved "services rendered . . . pursuant to medical judgment."

The conduct of the Premier Defendants is more akin to *Boldt* rather than *Hampton Hospital*. The essence of the unfair deceptive acts and practices under the New Jersey Consumer Fraud Act here arose from Premier Defendants ordering and obtaining for economic and convenience reasons, and not medical reasons, compounded prescription drugs from NECC through the knowing use of fraudulently written prescriptions that violated controlling Massachusetts substance laws and then falsely passing off and billing NECC's MPA as Depo-medrol, an FDA approved and controlled manufactured medication.[16] Premier's fraudulent prescription and billing practices in particular involved: (1) fraudulently using and listing the names of previous treated patients on NECC prescription order forms to bulk order office supplies of MPA, a practice that violates Massachusetts drug prescription laws[17]; and (2) knowingly passing off of NECC's cheaper compounded medication, preservative-free MPA, as Depo-medrol, as well as the false billing of less expensive MPA for the brand medicine. In sum,

[16] MGL 94C §§17, 19 and 22.

[17] *Ibid.* Premier's recent production of its prescription records for patients administered NECC MPA by its doctors in its facilities, including the Plaintiffs presently before the Court, shows that Premier Defendants systematically engaged in a long standing practice of ordering MPA and other drugs from NECC in bulk for office supply use in future upcoming procedures by submitting falsified prescriptions to NECC using the names of Premier patients who had already undergone injection with MPA. This violates Massachusetts laws governing the dispensing and distribution of compounded medicines. MGL 94C §§17, 19 and 22. Plaintiffs are prepared to provide declarations and documents supporting these claims.

Using past patient names by a healthcare practitioner to obtain or a pharmacy to dispense office supplies of a compounded controlled substance in 2012 also violated New Jersey's regulations that required prescriptions and prescription labels relate specific patients. N.J.A.C. 13:39-7.12(requiring patient name as part of labeling); N.J.A.C. 13:39-11.21 (Same); N.J.A.C. 13:35-7.2 (requiring a prescription to contain the patients full name, address and age. It also violates a patient's privacy rights under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) by disclosing patient names to another person (NECC) for purposes of other than the patients' treatment or care or billing for services. 42 U.S.C.A. § 1320d-6 ("A person who knowingly and in violation of this part . . . discloses individually identifiable health information to another person . . . shall be punished.")

shopping for and bulk ordering office supplies of routinely used medicine is simply too far removed from the exercise of medical skill and judgment that are the hallmarks of the learned professional exception as well as its *rationale d'être*.

In light of these principles and authorities, as applied to the facts alleged in Plaintiffs' complaint, it is clear that the learned professions exception should not apply to prevent Plaintiffs' claims under the CFA.

V. PLAINTIFFS' COMPLAINT CONTAINS SUFFICIENT FACTUAL ALLEGATIONS TO STATE A CLAIM FOR AGENCY.

The Premier Defendants contend that Count X of the Master Complaint should be dismissed for the following reasons: (1) there was no master-servant relationship between Premier and NECC; (2) Premier cannot be liable for the acts of its independent contractor, NECC; and/or (3) Premier is not responsible for the actions of NECC under the theory of apparent authority. In support of the aforementioned contentions, the Premier Defendants rely upon several cases: *Lowe v. Zarghami*, 731 A.2d 14 (N.J. 1999)(discussing the control test and the relative nature of the work test utilized by New Jersey Courts to determine whether an employer-employee relationship exists versus an independent contractor relationship); *Marek v. Professional Health Services, Inc.*, 432 A.2d 538 (N.J. Super. Ct. App. Div. 1981)(determining that the duty of the healthcare provider to competently diagnose a patient was a non-delegable duty); and *Estate of Cordero ex rel. Cordero v. Christ Hospital*, 958 A.2d 101 (N.J. Super. Ct. App. Div. 2008)(identifying factors to consider in determining whether the actions or inactions of a hospital would lead a patient to reasonably believe that the physician was rendering treatment on behalf of the hospital, i.e. the hospital held out the physician as its agent).

None of the cases cited by the Premier Defendants were decided pursuant to Motions to Dismiss, to the contrary, the decisions were made following the development of the an

evidentiary record through discovery. Here, Plaintiffs have not been provided an opportunity to develop an evidentiary record through discovery. However, assuming, *arguendo*, that the relationship between Premier and NECC was one of a principal and independent contractor, as the Defendants assert, New Jersey recognizes three (3) exceptions to the general rule that a principal/contractee is not liable for the negligence of an independent contractor: (1) where the principal retains control of the manner and means of doing the work which is the subject of the contract; (2) where the principal engages an incompetent contractor; or (3) where the activity contracted for constitutes a nuisance *per se*. *Majestic Realty Associates, Inc. v. Toti Contracting Co.*, 153 A.2d 231, 324 (N.J. 1959); *Mavrikidis v. Petullo*, 707 A.2d 977, 984 (N.J. 1998).

In the instant matter, the second exception set forth above justifies the imposition of vicarious liability upon the Defendants, whereas here, the Premier Defendants hired NECC, an incompetent contractor. To hold the Premier Defendants liable for the negligence of NECC it is necessary to show that (1) NECC was incompetent or unskilled to perform the job for which it was hired, and (2) that the Premier Defendants knew or had reason to know of NECC's incompetence. *Mavrikidis* at 137.

Plaintiffs' Master Complaint contains sufficient factual allegations to establish that the Premier Defendants can be held vicariously responsible for the acts of their independent contractor, NECC. Plaintiffs' allegations establish that NECC was not competent to prepare injectable steroids in bulk and that the Premier Defendants knew or had reason to know of NECC's incompetence. Specifically, Plaintiffs' Master Complaint alleges the following:

> 6. . . . these clinics ordered these medications (often with fake patient names), purchased the contaminated medications, received the contaminated medications, stored the contaminated medications, and injected the contaminated medications into patients—often dozens of patients. Clinics often disregarded the prevailing industry guidelines and Massachusetts Pharmacy Regulations requiring individual medications to be compounding in response to receiving a prescription for a particular patient. Clinics did so out of convenience and greed;

ordering large doses of injectable steroids in bulk allowed them to stock their shelves without going through the "hassle" (but really safeguard) of identifying particular patients who would receive the drug. And NECP's price for MPA was generally lower than the price for brand name methylprednisolone acetate (Depo Medrol) manufactured by Pfizer.

* * *

48. The serious risks of pharmacy compounding were the subject of considerable public discussion in the pharmacy community and in the medical community before the subject meningitis outbreak.

49. In 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report concluded that "purchasers of pharmaceuticals should if supplies are provided from a compounding pharmacy that. . . follows appropriate measures to ensure that injectable products are free of contamination."

50. On March 24, 2005, USA Today published a front page article with the following headline: "Safety concerns grow over pharmacy-mixed drugs." That article discussed growing concerns over the fact that drugs produced in bulk by compounding pharmacies are not FDA-approved and their not subject to the same oversight as drugs produced by pharmaceutical companies.

* * *

52. In May 2007, the FDA published an article titled: "The special risks of pharmacy compounding." That article highlighted numerous adverse event involving compounded products. It also warned of the emergence of large scale compounding operations that were clearly operating outside the bound of traditional compounding practice.

53. In 2010, the FDA posted an education video on YouTube regarding concerns over the quality of compounded drugs.

* * *

80. MDPH found that NECC distributed large batches of compound "sterile" products directly to facilities apparently for general use rather than requiring a prescription for an individual patient, in violation of its state pharmacy license.

81. NECC did not have patient-specific prescriptions from an authorized practitioner when compounding and dispensing medication, as required by state law.

* * *

157. The Clinic Related Defendants knew, or should have known, the importance of purchasing and administering safe and effective drugs to their patients, including Plaintiffs.

158. The Clinic-Related Defendants knew, or should have known, that one of the best ways of ensuring that it injects safe and effective drugs directly into the spinal canals, and other vulnerable places, of their patients was to use only drugs approved by the FDA for the intended form of administration.

* * *

162. The Clinic Related Defendants knew, or should have known, that NECC was not an FDA approved manufacturer.

163. NECC's un-regulated drugs were used by the Clinic Related Defendants in lieu of a commercially available drug products manufactured by FDA-regulated manufacturers.

* * *

165. It is a violation of the laws of the states of many of the Clinic Related Defendants, to sell compounded drugs in bulk and without a patient-specific prescription. NECC violated these laws.

* * *

167. The Clinic Related Defendants knew, or should have known, that NECC engaged in the process of producing and marketing very large quantities of its drugs.

* * *

170. The Clinic Related Defendants knew, or should have known, that NECC acted as a wholesale distributor by selling large quantities of its drugs to them, without being registered to do so within their states.

171. The Clinic Related Defendants knew, or should have known, that NECC was not registered to distribute prescription drugs wholesale in their state.

* * *

173. The Clinic Related Defendants knew, or should have known, that NECC engaged in the large-scale production and sale of its drugs without individual prescriptions in violation of state laws.

174. Notwithstanding the foregoing knowledge, many, if not all, of the Clinic Related Defendants voluntarily purchased drugs for use on the Plaintiffs on a wholesale basis from NECC without prescriptions.

175. Many, if not all, of the Clinic Related Defendants provided patient lists to NECC even though the patients on the lists did not necessarily receive the drug. Often times, the lists provided to NECC by the Clinic Related Defendants included false patient names.

* * *

180. The Clinic Related Defendants knew, or should have known, that another way of ensuring that safe and effective drugs are administered to their patients, including the Plaintiffs, was to purchase such drugs from an accredited compounding pharmacy or purchase pharmaceuticals directly from pharmaceutical manufacturers regulated by the FDA.

* * *

182. The Clinic Related Defendants knew, or should have known, that NECC was not an accredited compounding pharmacy.

Additionally, Count X – Agency of Plaintiffs' Master Complaint, alleges, the following:

> 329. All allegations above are incorporated herein by reference.
>
> 330. At all times relevant herein, NECC was acting as an agent of the Clinic Related Defendants in compounding drugs to be administered to the Plaintiffs by the Clinic Related Defendants.
>
> 331. A consensual fiduciary relationship arose when the Clinic Related Defendants contracted with NECC to procure compounded drugs from NECC for their patients, including Plaintiffs.
>
> 332. The Clinic Related Defendants manifested assent for NECC to act as their agent, and on their behalf, when the Clinic Related Defendants contracted with NECC to procure compounded drugs from NECC to administer to their patients, including Plaintiffs.
>
> 333. NECC consented to act as the Clinic Related Defendants' agent, and in the Clinic Related Defendants' interest, when compounding, selling and delivering its compounded drugs to the Clinic Related Defendants, to be sold and administered to the Clinic Related Defendants' patients, including the Plaintiffs.
>
> 334. At all times relevant herein, NECC acted within the scope of its agency with the Clinic Related Defendants. As set forth herein, NECC acted negligently and or exhibited gross negligence in the compounding of NECC contaminated drugs.
>
> 335. The Clinic Related Defendants controlled the procurement of the drugs from NECC to be sold and administered to their patients, including the Plaintiffs.
>
> 336. As a result, the Clinic Related Defendants are responsible for the negligence, gross negligence and wrongful conduct of NECC in compounding the contaminated drugs administered to Plaintiffs.

(See Master Complaint.)

Thus, under the applicable New Jersey law, and viewing any reasonable inferences from the factual allegations contained in the Plaintiffs' Master Complaint in the light most favorable to Plaintiffs, Plaintiffs have set forth a claim of agency against the Premier Defendants.

VI. THE MASTER COMPLAINT HAS SUFFICIENTLY STATED A CLAIM FOR PUNITIVE DAMAGES UNDER THE NEW JERSEY PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15-5.9, *ET SEQ*.).

Premier Defendants also seek dismissal of Count XIV of the Master Complaint for punitive damages. Defendants contend that Plaintiffs have failed to set forth sufficient facts to support a claim for punitive damages because they argue that Plaintiffs have merely asserted that Premier Defendants acted recklessly, which is insufficient to award punitive damages. However, there is no basis for striking Plaintiffs' request for punitive damages at this juncture

because the Master Complaint is replete with factual allegations demonstrating that Defendants' conduct was willful and wanton and beyond mere negligence or gross negligence. At this stage in the litigation, Plaintiffs' claims for punitive damages should not be dismissed.

Punitive damages are available in New Jersey under the Punitive Damages Act, N.J. Stat. Ann. § 2A:15-5.9 *et seq*. Under the Act, punitive damages may be awarded when a plaintiff demonstrates that he suffered harm from a defendant's acts or omissions that were "actuated by actual malice or accompanied by a wanton and willful disregard for persons who foreseeably might be harmed by those acts or omissions." § 2A:15-5.12(a); see also *Nappe v. Anschelewitz, Barr, Ansell & Bonello*, 97 N.J. 37, 477 A.2d 1224, 1230 (N.J. 1984) ("To warrant a punitive award, the defendant's conduct must have been wantonly reckless or malicious).

Despite Defendants' contentions in their Motion to Dismiss, Plaintiffs have indeed asserted that Defendants' conduct showed a wanton and willful disregard for its patients. In fact, with respect to Defendants' wanton and willful conduct, the Complaint states in pertinent part:

> 237. The foregoing acts and omissions by the Clinic Related Defendants went beyond mere thoughtlessness, inadvertence or error of judgment.
>
> 238. The actions of the Clinic Related Defendants did not meet even the most minimal diligence to ensure that they were not injecting contaminated, adulterated, tainted, and unreasonably dangerous drugs directly into the bodies of their patients, including Plaintiffs.
>
> 239. The acts and omissions of the Clinic Related Defendants constituted such utter disregard for the rights of others, and such utter disregard for prudence, that they amount to complete neglect of the safety of patients, including Plaintiffs.
>
> * * *
>
> 249. Clinic Related Defendants ***willfully and knowingly*** failed to abide by regulations, laws and guidelines set forth to protect consumer safety, constituting a violation of the consumer protection statutes set forth herein.
>
> 250. Clinic Related Defendants' ***willful and knowing*** withholding of important safety information and critical product information constitutes a violation of various state consumer protection statutes set forth herein.

> 251. Clinic Related Defendants ***actively, knowingly, and deceptively*** concealed the product's dangerous properties and life-threatening risks of which they knew or should have know [sic]. This conduct evidences bad faith and unfair and deceptive practices.

(Master Complaint)(Emphasis added).

Because Plaintiffs have alleged that Defendants' actions were accompanied by willful disregard for patients and because such conduct went beyond mere "thoughtlessness, inadvertence or error of judgment," Plaintiffs have adequately and sufficiently stated a claim under the New Jersey Punitive Damages Act for punitive damages at this stage of this case.

VII. PLAINTIFFS SHOULD BE PROVIDED THE OPPORTUNITY TO AMEND THEIR MASTER COMPLAINT.

Even assuming, *arguendo*, that this Honorable Court concludes that the factual allegations against Premier Defendants were inadequately pleaded, the Federal Rules of Civil Procedure direct courts to freely provide the opportunity to amend a complaint: "The court should freely give leave when justice so requires." Fed. R. Civ. P. 15(a). If a complaint is subject to dismissal per Fed. R. Civ. P. 12(b)(6), leave should be given to amend unless doing so would be inequitable or futile. *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 245 (3d Cir. 2008). Plaintiffs ask that this Honorable Court provide an opportunity to amend their Complaints should the Court deem it necessary.

CONCLUSION

For the aforementioned reasons, the Premier Defendants' Motion to Dismiss should be denied in its entirety. Should the Court grant the motion to dismiss, the Plaintiff requests that the dismissal be without prejudice and/or with leave to file an amended complaint as requested above.

Dated: March 7, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Steven D. Resnick, hereby certify that I caused a copy of the above Plaintiffs' Steering Committee's Memorandum of Law in Opposition to Premier Defendants' Motion to Dismiss Pursuant to F.R.C.P. 12(b)(6) to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: March 7, 2014

/s/ Steven D. Resnick
Steven D. Resnick, Esquire